

REMARKS

Claims 1-3, 7, and 9 are pending and under examination. The claims have been rejected under 35 U.S.C. 103 as obvious over Cook et al. (US Pat. No. 5,554,646) in view of Kawamura et al. (Hypertension 27:408-413 (1996)) and Shinitzky et al. (US Pat. No 4,474,773). The Examiner states that Cook et al. discloses a method of reducing body fat by administering CLA. The Examiner has previously admitted that Cook et al. does not teach the use of CLA to treat hypertension. The Examiner states that Kawamura et al. teach that reduction in body weight in overweight human patients correlates to a reduction in hypertension and that this provides a "nexus teaching between hypertension, weight loss and decreases in blood pressure." Office Action at p. 3. This essentially repeats the reasoning of the prior office action. The Examiner has cited a new reference, Shinitzky et al. The Examiner states that Shinitzky et al. teaches methods of treating warm-blooded mammals comprising administering a pharmaceutically acceptable amount of a composition comprising 5-10% linoleic acid for the treatment of hypertension and specifically refers to 1, 4, and 24.

At the outset, Applicants respectfully submit that the Examiner has misstated the scope and content of the prior art. In particular, the Examiner's characterization of Shinitzky is incorrect and is not consistent with the meaning one of skill in the art would give the reference. The Examiner states that Shinitzky teaches that hypertension can be treated by administering a composition comprising 5-10% linoleic acid and refers to claims 1, 4 and 24. The Examiner's attention is respectfully directed to declaration of Inge Bruheim. What those claims teach is that hypertension can be treated by administering a complex mixture comprising "a lipid fraction derived from natural sources (AL), said lipid fraction containing 40-80 weight percent glycerides, 3-5 weight percent cholesterol, 10-30 weight percent lecithin (phosphatidyl choline), 5-15 weight percent phosphatidyl ethanolamine and 2-5 weight percent negatively charged phospholipids, wherein the ratio of unsaturated to saturated fatty acids is at least 1:1" (Claim 1) and that the fatty acid component of this complex mixture comprises "Palmitic acid 35-45%, oleic acid 35-45%, linoleic acid 5-10%, stearic acid 5-7%, palmitoleic acid 2-3%, arachidonic acid 0.2-1%" (Claim 4). According to Dr. Bruheim, the reference does not teach that any composition comprising 5-10% linoleic acid can be used to treat hypertension or that among all of the components of the complex mixture, linoleic acid is sufficient to treat hypertension.

Indeed, the complex mixture has many other components which could be causing the reduction in hypertension.

The Examiner goes on to state that the claims are prima facie obvious because 1) Cook et al. provide a method of reducing body fat, 2) Kawamura et al. teaches that reduction in weight results in lowering of blood pressure and 3) Shinitzky et al. teach that linoleic acid can be used to treat hypertension. First, as explained above, Shinitzky does not teach that linoleic acid can be used to treat hypertension. Shinitzky teaches that a complex lipid fraction containing many components can be used to treat hypertension.

The Examiner further states that “since conjugated linoleic acid is a mixture of positional and geometric isomers of linoleic acid, then one of ordinary skill in the art would immediately envision the use of conjugated linoleic acid in the treatment of hypertension. In fact, similar properties may normally be presumed when compounds are very close in structure.” As pointed out in Dr. Bruheim’s declaration, this argument is scientifically invalid with respect to conjugated linoleic acid and linoleic acid. First, Shinitzky does not teach that linoleic acid can be used to treat hypertension. Second, it is well established in the art that conjugated linoleic acid and c9,c12 linoleic acid have different biological properties. One of skill in the art knows this. Thus, even if were true that Shinitzky teaches that standard c9,c12 linoleic acid can be used to treat hypertension, one of skill in the art would not think that c9,c12 linoleic acid and conjugated linoleic acid have the same biological property of being useful for treating hypertension. The presumption of obviousness based on a reference disclosing structurally similar compounds is overcome where there is evidence showing there is no reasonable expectation of similar properties in structurally similar compounds. In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (appellant produced sufficient evidence to establish a substantial degree of unpredictability in the pertinent art area, and thereby rebutted the presumption that structurally similar compounds have similar properties). Dr. Bruheim’s Declaration provides such evidence.

In addressing Applicant’s previous arguments, the Examiner disagrees with the statements in the Saeco Declaration and argues that since the “art recognizes linoleic acid in a method of treating hypertension” that it “remains obvious to one of ordinary skill in the art that the method of Cook et al. can lower blood pressure via administration of conjugated linoleic acid because the positional and geometrical isomers of linoleic acid would be expected to have

similar properties in the absence of evidence to the contrary.” First, the Saebo Declaration establishes that the action of conjugated linoleic acid in the body is complex, and thus unpredictable. The Examiner has not rebutted or addressed this fact and it is directly relevant to whether conjugated linoleic acid can be expected to behave the same way as linoleic acid. Second, as established in the Bruheim Declaration, the art does not recognize that standard c9,c12 linoleic acid can be used to treat hypertension. Third, the Bruheim Declaration provides evidence that conjugated linoleic acid and standard c9,c12 linoleic acid cannot be expected to have the same properties.

Accordingly, Applicants respectfully submit that the Examiner has not established a prima facie case of obvious and that the rejection should be withdrawn.

CONCLUSION

It is respectfully submitted that the invention as claimed fully meets all requirements for patentability and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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